

REMARKS

In the Final Office Action mailed September 28, 2007, claims 1-14, 44-64, 67 and 69 are actually pending based on the claims submitted in the previous response dated July 13, 2007. Claims 1, 5-7, 11-14, 44-47, 51-57, 60—64, 67 and 69 appear to stand rejected. It is noted for the record, as also noted in the previous response, the Final Office Action fails to provide an accurate summary of the pending claims in this application. The Final Office Action fails to identify the withdrawn claims 2-4, 8-10, 48-50 and 58-59, which remain pending in this application and have not been cancelled by the applicants. The Final Office Action also fails to identify claims 6, 46, or 57 as pending or rejected in the Office Action Summary, but does provide a basis for rejecting these claims in the Detailed Action. An accurate listing of the pending claims and the withdrawn status of claims 2-4, 8-10, 48-50 and 58-59 in the next action is respectfully requested.

In this response, claims 1, 44 and 55 have been amended. Reconsideration of the present application as amended and including claims 1-14, 44-64, 67 and 69 is respectfully requested.

Regarding claims 8-10, 48-50, 58 and 59, the Examiner previously asserted that these claims did not belong to the elected species. This assertion has been traversed, such as in the response dated January 22, 2007, and no reply or rebuttal to the traversal has been provided by the Examiner. The Restriction Requirement did not identify Figures 3 and 4 as a separate species, and Applicant was therefore entitled to respond to the Restriction Requirement on the basis that Figures 3 and 4 were not a separate species since the Examiner did not identify Figures 3 and 4 as a separate species. Furthermore, Figures 3 and 4 illustrate additional features of the elected species and the application clearly discloses that reduction elements having the features shown in Figs. 3 and 4 can be employed with the elected Species I. *See, e.g.,* page 9, line 20 to page 10, line 8 of the specification.

Furthermore, the Examiner previously asserted that "Applicant never mentions that Figs. 3 and 4 (sic) belong to the elected species". In responding to the Restriction Requirement, Applicant did indeed assert that claims 8-10, 48-50 and 58-59 read on the elected species and thus the Applicants did consider that Figures 3 and 4 belonged to the elected species. *See* the "Amendment and Response to Restriction/Election Requirement"

dated December 15, 2004, page 7, lines 14-17. Under the species election set forth by the Examiner, there could be no election of the species identified in the Restriction Requirement that would allow claims 8-10, 48-50 and 58-59 to be examined in the present application. Therefore, it was reasonable to conclude that there was no intention by the Examiner to set forth Figures 3 and 4 as a separate species since Figures 3 and 4 merely illustrate additional features of the elected species, and the specification clearly discloses that Figures 3 and 4 are included with at least the elected species of Figures 1 and 2. Therefore, the election of species was proper, claims 8-10, 48-50, 58 and 59 were identified as reading on the elected species, and examination of claims 8-10, 48-50, 58 and 59 in this application based on the species election is therefore proper and respectfully requested.

Claim 1, 44 and 55 were rejected as being anticipated by U.S. Patent No. 5,571,189 to Kuslich. Claims 1, 44 and 55 have been amended to recite "wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body...." Support for the amendments can be found at least in Figures 1-2 and at page 8, line 20 to page 9, line 13, for example.

In rejecting previous claim 1, the examiner asserts that the prior art still reads on the new limitations. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983) holds "it is only necessary that the claims under attack, as construed by the court, 'read on' something disclosed in the reference, i.e. all limitations of the claim are found in the reference, or 'fully met' by it" Id. at 790. Therefore, it is necessary for the examiner to consider all the limitations of the claim in the manner arranged in the claim, and an anticipation rejection can only be supported of all if these limitations can be read on the prior art.

Kuslich discloses a bag 40 with a chamber 44 that is positioned between vertebrae to provide for fusion of adjacent vertebrae through the spinal disc space. Chamber 44 is filled with graft medium 52 to facilitate fusion or fibrous union between opposing vertebrae 12, 14. The graft medium 52 includes finely chopped cortical or cancellous bone chips for fusion or connective tissue when a fibrous union is desired. *See* col. 9, lines 53-58. The examiner cannot properly read "wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores

the vertebral body" since there is no disclosure that chamber 44 or the morselized bone graft is selected in number to occupy a volume within an intravertebral to reduce a fracture or restore the vertebral body. Therefore, Kuslich cannot anticipate claims 1, 44 and 55 and withdrawal of the rejection of these claims is respectfully requested.

Furthermore, there is no disclosure that the bone chips act sequentially one upon the other to apply an outwardly directed in an intravertebral space to restore a vertebral body. The bone chips are contained in a medium that is positioned into bag 44 under pressure in a single step in a spinal disc space. The examiner has not explained nor is it found in Kuslich that the bone chips in the pressurized medium would or could be capable of acting sequentially one upon the other to apply an outwardly directed in an intravertebral space to restore a vertebral body. Rather, Kuslich discloses a pressurized medium to distract vertebrae. Furthermore, with respect to claim 1, Kuslich fails to disclose any "means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said means including material filling said voids and locking said plurality of reduction elements relative to one another" as recited in amended claim 1. Claims 44 and 55 recite material that rigid fix the volume of the reduction elements to maintain the restored intravertebral space, and also are not disclosed by Kuslich. Accordingly, withdrawal of this basis of the rejection of claims 1, 44 and 55 is respectfully requested.

Claims 1, 5, 7, 11-14, 44, 45, 47, 51-56 and 60-69 were indicated to be rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,755,797 to Baumgartner in view of U.S. Patent No. 6,620,196 to Trieu. As discussed above, this listing of claims does not appear to be accurate since the rejections discussed later on pages 4-6 of the Detailed Action do not correspond to the claim listing on page 4.

Baumgartner does not disclose or teach that the support members 7 "are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body...." Rather, support members 7 are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae for movement. Furthermore, the volume occupied by support members 7 is not fixed since Baumgartner further teaches that "during loading, the support members are elastically

deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus." See col. 1, line 62-65. The compression of the elastic support members 7 prevents fixing of the volume occupied by the support members 7.

Furthermore, Trieu fails to remedy the deficiencies of Baumgartner since Trieu teaches a load bearing elastic body that is housed in an outer shell. The elastic body in Trieu provides an implant with shape memory configured to allow extensive short term manual or other deformation without permanent deformation, cracks, tears, breakage or other damage. See col. 2, line 66 to col. 3, line 3. Trieu further teaches that the dimensions of the implant are sized to reside within a disc space between vertebrae. See col. 5, line 56 to col. 6, line 13. Trieu teaches that shell 30 is in contact with and bonded to elastic body 15 so that "the elastic body is in some way anchored, or otherwise fixed in place, by the outer shell so as to prevent its expulsion from, or excessive migration in, the disc cavity." See col. 5, lines 24-27. The teaching of fixing the position of elastic body 15 does not teach fixing its volume. Furthermore, Trieu teaches that outer shell 30 "may be formed from a wide variety of biocompatible, preferably elastic, elastomeric or deformable natural or synthetic materials..." See col. 6, lines 62-65. Accordingly, Trieu teaches an elastic body 15 and a deformable outer shell 30 that varies in volume in response to spinal loading and movement. There is no teaching or suggestion in Trieu that outer shell 30 rigidly fixes components of elastic body 15 to one another, or that shell 30 fills voids between components of elastic body 15 to lock components of elastic body 15 relative to one another, or that shell 30 fixes a volume of the elastic body or any other component positioned therein. If elastic support members 7 of Baumgartner were combined with shell 30, the combination of references includes these same deficiencies, and the combination of references fails to teach or suggest all the elements of claim 1, including "means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another" that includes "material filling said voids and locking said plurality of reduction elements relative to one another." Therefore, claim 1 is allowable.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claim 44. As discussed above, Trieu teaches an elastic body 15 and a deformable outer shell 30. There is no teaching or suggestion in Trieu that outer shell 30 rigidly fixes components of elastic body 15 to one another, that shell 30 fills voids between components of

elastic body 15 to lock components of elastic body 15 relative to one another, or that shell 30 fixes elastic body 15 at a volume or could fix elastic support members 7 of Baumgartner at a volume. Trieu therefore fails to remedy the deficiencies of Baumgartner, and the combination of references fails to teach or suggest all the elements of claim 44, including "material filling said voids and rigidly fixing said plurality of reduction elements in said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another."

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claim 55. As discussed above, Trieu teaches an elastic body 15 and a deformable outer shell 30. There is no teaching or suggestion in Trieu that outer shell 30 rigidly fixes components of elastic body 15 to one another, that shell 30 fills voids between components of elastic body 15 to lock components of elastic body 15 relative to one another, or that shell 30 fixes elastic body 15 at a volume or could fix elastic support members 7 of Baumgartner at a volume. Trieu therefore fails to remedy the deficiencies of Baumgartner, and the combination of references fails to teach or suggest all the elements of claim 55, including "material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another."

Furthermore, Baumgartner teaches away from any "means for rigidly fixing said plurality of reduction elements in engagement with one another" that includes "material filling said voids and locking said plurality of reduction elements at said volume relative to one another." Such an arrangement would render Baumgartner unsuitable for its intended purpose since Baumgartner teaches that "during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus." See col. 1, line 62-65. Rigidly fixing the support members at a volume relative to one another and locking the support members relative to one another runs counter to the teachings of Baumgartner. Trieu also teaches an elastic support structure and fails to remedy these deficiencies. Therefore, Baumgartner teaches away from

any modification thereof that would properly support an obviousness rejection of claims 1, 44 or 55.

Claims 5-7, 11-14, 45-47, 51-54, 56-57, and 60-64, 67, and 69 depending from claims 1, 44 and 55 were rejected as being unpatentable over Baumgartner in view of Trieu are allowable at least since the claim from which each depends is allowable and for other reasons. Claims 67 and 69 depend from claims 1 and 44, respectively, and each recites "wherein said plurality of reduction elements are selected to occupy sufficient intravertebral space to restore a height of the vertebral body between endplates thereof." There is no indication of how these features are disclosed or taught in either Baumgartner or Trieu, and therefore a prima facie case for rejecting either of claims 67 or 69 has not been established. Furthermore, both Baumgartner and Trieu teach devices selected to occupy an intervertebral or spinal disc space between vertebrae, but not an intravertebral space. Therefore, withdrawal of the rejection of dependent claims 5-7, 11-14, 45-47, 51-54, 56-57, and 60-64, 67, and 69 is respectfully requested.

Reconsideration and allowance of the present application as amended and including claims 1-14 and 44-64, 67, and 69 is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

Respectfully submitted

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